Becton Dickinson Infusion Therapy Systems Inc.
9450 South State Street
Sandy, Utah 84070 USA

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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Becton Dickinson Infusion Therapy Systems Inc.
Manufacturer address and contact details	9450 South State Street Sandy, UT 84070 USA
Single Registration Number (SRN) (if available)	US-MF-000017719

Authorised Representative name (if applicable)	Becton, Dickinson and Company Limited
Authorised Representative address and contact details	Donore Road Drogheda Co. Louth Ireland A92 YW26 Ireland
Single Registration Number (SRN) (if available)	IE-AR-000007610

Notified body name (if applicable)	See attached schedule
Notified body number (if applicable)	See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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Directive Certificate number(s) to which this confirmation is made (if applicable)	See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	See attached schedule
End date of extended validity/transition period	See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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✓ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

✓ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
✓ A QMS in accordance with Article 10(9) MDR is in place.
☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

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Signed for and on behalf of the manufacturer:

DocuSigned by:

Signer Name: Casey Coombs
Signing Reason: I approve this document
Signing Time: 18-Dec-2023 | 6:16:53 AM PST
50B5409A613043808E41FF9FAF7676B8

Casey Coombs, Associate Director, Regulatory Affairs

Becton Dickinson Infusion Therapy Systems Inc.

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
381112	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381123	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381134	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381137	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381144	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381147	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381154	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381157	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381164	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381167	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382258	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382259	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382268	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382269	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382277	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382287	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381211	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381212	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381223	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381233	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381234	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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381237	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381244	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381247	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381254	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381257	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381267	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381311	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381312	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381323	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381333	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381334	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381337	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381344	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381347	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381354	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381357	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382412	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	BD Insyte™ I.V. Catheter
382423	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	BD Insyte™ I.V. Catheter
382434	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	BD Insyte™ I.V. Catheter
382437	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	BD Insyte™ I.V. Catheter
382444	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	BD Insyte™ I.V. Catheter
382447	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	BD Insyte™ I.V. Catheter
382457	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	BD Insyte™ I.V. Catheter
381811	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381812	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381823	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381833	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381834	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381837	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

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381844	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381847	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381854	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381857	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381867	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381911	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381912	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381923	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381933	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381934	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381937	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381944	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381947	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381954	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381957	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381012	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381023	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381024	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381033	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381034	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381037	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381044	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381047	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381054	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
381057	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382912	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382923	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382924	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382933	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382934	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382937	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382944	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382947	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382954	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
382957	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

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391660	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
391661	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
391663	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
391662	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386900	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386901	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386801	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386802	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386803	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386804	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386805	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386806	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386807	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386910	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386911	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386808	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386809	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386810	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386811	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386812	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386813	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386814	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386815	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386816	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386817	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386818	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386819	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386820	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
386821	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383590	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383591	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383592	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383593	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383594	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383691	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

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383692	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383693	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383694	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383695	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
682245	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
384021	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
384030	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
384031	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
384040	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
384050	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383312	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383313	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383318	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383319	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383322	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383323	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383328	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383329	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383335	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383336	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383338	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383339	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383346	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383348	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383510	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383511	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383512	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383513	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383516	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383517	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383518	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383519	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383520	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383530	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383531	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

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383532	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383533	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383534	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383535	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383536	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383537	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383538	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383539	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383540	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383550	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383551	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383552	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383553	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383556	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383557	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383558	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383559	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383560	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383570	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383571	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383572	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383573	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383576	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383577	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383578	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383579	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383580	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383640	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383641	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383642	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383646	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383647	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383648	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383649	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383650	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

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383660	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383661	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383662	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383666	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383667	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383668	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383669	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383670	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383680	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383681	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383682	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383686	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383687	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383688	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383689	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
383690	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

Becton Dickinson Infusion Therapy Systems Inc.
9450 South State Street
Sandy, Utah
84070
USA

December 7, 2023

Notified Body Confirmation Letter

Reference: EU2023-607/722094

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Becton Dickinson Infusion Therapy Systems Inc.
9450 South State Street
Sandy, Utah 84070
USA
SRN Number (if available): US-MF-000017719

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Luis Martinez

BSI Scheme Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
BD Angiocath™ I.V. Catheter	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Angiocath™ I.V. Catheter for Special Placement	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Insyte-N™ I.V. Catheter	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Insyte-N™ I.V. Catheter with Wings	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Insyte™ I.V. Catheter	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Insyte™ I.V. Catheter	Class IIa	BD Angiocath Plus™ I.V. Catheter	Certificate CE 01738; NB# 2797
BD Insyte-W™ I.V. Catheter with Wings	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Insyte™ Autoguard™ BC Pro Shielded I.V. Catheter	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Insyte™ Autoguard™ BC Pro Winged Shielded I.V. Catheter	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Insyte-N™ Autoguard™ Shielded I.V. Catheter	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Insyte-N™ Autoguard™ Winged Shielded I.V. Catheter	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Insyte™ Autoguard™ Shielded I.V. Catheter	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Insyte™ Autoguard™ Winged Shielded I.V. Catheter	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Neoflon™ Pro Safety I.V. Catheter	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Neoflon™ Pro Safety I.V. Catheter with Wings	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
BD Cathena™ Safety I.V. Catheter	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Cathena™ Safety I.V. Catheter with Wings	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Nexiva™ Diffusics™ Closed I.V. Catheter System	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Arterial Cannula	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Introsyte™ Introducer	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Introsyte-N™ Introducer	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Saf-T-Intima™ Closed I.V. Catheter System	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Nexiva™ Closed I.V. Catheter System	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Nexiva™ Closed I.V. Catheter System – Single Port	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797
BD Nexiva™ Closed I.V. Catheter System – Dual Port	Class IIa	Not Applicable	Certificate CE 01738; NB# 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/12/07	Initial issue

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton Dickinson Infusion Therapy Inc. 9450 South State Street Sandy, Utah 84070, USA
Authorised Representative:	Becton Dickinson Distribution Center NV Laagstraat 57, B-9140 Temse, Belgium
Manufacturing Site(s):	Becton Dickinson Infusion Therapy Inc. S.A. de C.V. Periferico Luis Donaldo Colosio #579 Nogales Sonora, C.P.84048, Mexico Becton Dickinson Medical Devices Co., Ltd. Suzhou No. 5 Baiyu Road, Suzhou Industrial Park Jiangsu P.R. China
Products:	383312 BD Saf-T-Intima™ Safety System with Removable PRN (24 GA 0.75 IN) 383313 BD Saf-T-Intima™ Safety System with Y Adapter (24 GA 0.75 IN) 383318 BD Saf-T-Intima™ Safety System with Removable PRN (24 GA 0.75 IN) 383319 BD Saf-T-Intima™ Safety System with Y Adapter (24 GA 0.75 IN) 383322 BD Saf-T-Intima™ Safety System with Removable PRN (22 GA 0.75 IN) 383323 BD Saf-T-Intima™ Safety System with Y Adapter (22 GA 0.75 IN) 383328 BD Saf-T-Intima™ Safety System with Removable PRN (22 GA 0.75 IN) 383329 BD Saf-T-Intima™ Safety System with Y Adapter (22 GA 0.75 IN) 383335 BD Saf-T-Intima™ Safety System with Removable PRN (20 GA 1.00 IN) 383336 BD Saf-T-Intima™ Safety System with Y Adapter (20 GA 1.00 IN) 383338 BD Saf-T-Intima™ Safety System with Removable PRN (20 GA 1.00 IN) 383339 BD Saf-T-Intima™ Safety System with Y Adapter (20 GA 1.00 IN) 383346 BD Saf-T-Intima™ Safety System with Y Adapter (18 GA 1.00 IN) 383348 BD Saf-T-Intima™ Safety System with Y Adapter (18 GA 1.00 IN)
Classification:	Class IIa under Rule 7 of Annex IX of the Council Directive 93/42/EEC, as amended
Conformity Assessment Route:	Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4
GMDN Information:	REF 383312, 383313, 383322, 383323, 383335, 383336, 383346, 383338, 383339, 383348 GMDN Code: 64574 GMDN Term: Peripheral intravenous cannula GMDN Definition: A short, thin tube intended to be inserted into a peripheral vein (typically on the hand/arm) to enable short-term (< 30 days) intravenous (IV) access for administration of fluids/medication and blood sampling. Also referred to as a peripheral IV catheter, it is typically assembled with a dedicated introduction needle, and usually includes connectors, injection ports, and wings for fixation. It is not intended to be advanced to the central vasculature. This is a single-use device. REF 383318, 383319, 383328, 383329 GMDN Code: 61650

	GMDN Term: Peripheral vascular/ subcutaneous catheter GMDN Definition: A sterile, dual-purpose, thin, flexible tube intended for: 1) insertion into the peripheral vasculature to enable short-term (< 30 days) intravascular access for blood sampling, blood pressure monitoring, fluid/medication administration and/or contrast media injection; and 2) administration of fluids/medication into subcutaneous tissue. It typically includes dedicated accessories to facilitate catheter introduction/function (e.g., connectors, injection ports, stylet, fixation wings, introduction needle). This is a single-use device.

We herewith declare that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. All supporting documentation is retained at the premises of the manufacturer.

Harmonised Standards:	EN ISO 14971:2012 (ISO 14971:2007, Corrected version 2007-10-01) EN ISO 13485:2016 (ISO 13485:2016) EN 20594-1:1993 (ISO 594-1:1986) EN ISO 10555-1:2009 (ISO 10555-1:2013) EN ISO 10993-1:2009 (ISO 10993-1:2009) EN ISO 10993-7:2008 (ISO 10993-7:2008) EN ISO 11607-1:2009 (ISO 11607-1:2006) EN ISO 11607-2:2006 (ISO 11607-2:2006) EN ISO 11135-1:2007 (ISO 11135-1:2014) EN 556-1:2001 EN ISO 15223-1:2016 (ISO 15223-1:2016, Corrected version 2017-03) EN 1041:2008 EN 15986:2011
Non-Harmonised Standards:	ISO 594-2:1998 ISO 10555-5:2013
Notified Body:	BSI Say Building, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands Notified Body Number: 2797
EC Certificate Number:	CE 01738
Date of issuance of the original CE certificate:	03 October 1997

Date: 2021-04-27

Roya Borazjani

Roya Borazjani
VP, Regulatory Affairs
Becton Dickinson Infusion Therapy Systems Inc.

VERSION HISTORY

Current Version Prepared By: Andrea Tiede

Version	Version Description
I	Manufacturing Site(s): Added Becton Dickinson Medical Devices Co., Ltd. Suzhou (China) as an additional manufacturing site. Harmonised Standards: Removed withdrawn standard ISO 10555-1:1995 and replaced with ISO 10555-1:2013.
H	CE 01738 renewed (expiration date: 26-May-2024). Header: added “TM” to product name.
G	GMDN: Updated the GMDN code, term, and definition for REF 383312, 383313, 383322, 383323, 383335, 383336, 383346, 383338, 383339, 383348 with replacement GMDN code 64574.